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10/019,436	12/31/2001	Akira Yazaki	217151US0PCT	4227

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OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EXAMINER
MORRIS, PATRICIA L

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/019,436	Applicant(s) Yazaki et al
	Examiner P. Morris	Group Art Unit 1625

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 1-7 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsp rson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

DETAILED ACTION

Claims 1-7 are under considersation in this application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3, 5 and 6 are rejected under 35 U.S.C. 101 and 35 U.S.C. 112 because the claimed invention is directed to non-statutory subject matter. Claim 7 violates 35 U.S.C. 101 and 35 U.S.C. 112, since it is drafted in terms of use. See Clinical Products vs. Brenner, 255 F. Supp. 151; 149 USPQ 475 (D.C. District of Columbia 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being obvious over the combined teachings of Yazaki et al. I (WO 97/11068), II (US 5,988,436).

The applied reference US 5,988,436 has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the

claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Yazaki et al. I, II generically embrace the instant compounds having the same use. Note for example the compounds of formula (I) wherein R^1 represents hydrogen, R^5 represents an alkyl substituted azetidin-1-yl group, Y is nitrogen and R^3, R^4, R^7, R^8 represent halogen.

It is believed that one having ordinary skill in the art would have found the claimed compounds *prima facie* obvious, since they are generically embraced by the disclosed formula; In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See also In re Malagari, 499 F.2 1297, 182 USPQ 549 (CCPA 1974); In re Lemin, 332 F.2d 839, 141 USPQ 814 (CCPA 1964); In re Rosicky, 276 F.2d 656, 125 USPQ 341 (CCPA 1960). The requisite motivation for arriving at the claimed compounds stems from the fact that they fall within the generic class of compounds disclosed by Yazaki et al. I, II. Accordingly, one having ordinary skill in the art would have been motivated to prepare any of the compounds embraced by the disclosed generic formula, including those encompassed by the claims, with the expectation that each of them would be suitable as antibacterial agents.

It is believed well settled that a reference may be relied upon for all that it would have reasonably conveyed to one having ordinary skill in the art. In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); In re Lamberti, 545 F.2d 747, 192 USPQ 278 (CCPA 1976); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); In re Susi, supra.

Further, Yazaki et al. I, II teach a compound differs from the compound claimed herein as a alkyl homolog. Note example 75 and claim 9 of Yazaki et al. I. One having ordinary skill in the art would have been motivated by the disclosure of the prior art compound to arrive at the claimed compound. The motivation to make the instant compound is its close structural similarities to the disclosed compound. Note that the disclosed compound has antibacterial activity, thus the skilled artisan would expect such structurally similar compounds to possess similar properties. While homology is considered to be present even if true "homology" is not present, such does not defeat the prima facie case of obviousness raised by the art. Attention, in this regard is directed to In re Druey et al., 50 CCPA 1538, 319 F.2d 237, 138 USPQ 39, wherein Judge Worley, delivering the Court's opinion, stated:

> "We need not decide here whether the compounds in question are properly labeled homologues. It appears to us from the authorities cited by the solicitor and appellants that the term homologue is used by chemists at times in a broad sense, and at other times in a narrow or strict sense. The name used to designate the relationship between the related compound is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound." 50 CCPA 1541.

Also, as the Court stated in In re Payne et al., 606 F.2d 302, 203 USPQ 245 at 255 (CCPA 1979):

> "the name used to designate the relationship between related compounds is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound."

In addition, any question of why would one conceive and use the similar compounds (*i.e.* "motivation") is answered by the Court in In re Gyurik et al., 596 F.2d 1012, 201 USPQ 552 at 557.

> "In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness, rises from the expectation that compounds similar in structure will have similar properties."

Claim Rejections - 35 USC § 112

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating bacterial infections, does not reasonably provide enablement for the treatment of any and all infectious diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

No enablement is shown for the treatment of all infectious diseases. The tests set forth on of any and all infectious diseases.

The disclosure provides no indication of whether the compounds treat all infectious diseases. Is malaria treated?

As pointed out in In re Schmidt, 377 F.2d 639, 153 USPQ 640 (CCPA 1967), lack of specificity about the medicinal properties and specific effects of claimed compounds is not outweighed by a detailed "boiler plate" recitation of conventional techniques limited to the manner in which the compounds may be formulated and administered. The disclosure must inform those skilled in the art how to use the invention, not merely invite them to find out for themselves how to use it. See also In re Moureu, 345 F.2d 519, 145 USPQ 452 (CCPA 1965).

Issenstead v. Watson, (DCDC 1957) 157 F Supp. 7, 115 USPQ 408 and Schindler v. Comr. of Pats. (DCDC 1967) 269 F Supp. 630, 155 USPQ 838. Noted where an application discloses therapeutic effect on humans or a cure for a human disease as the utility of a claimed process, the District Court held that proof of such utility is required unless one of ordinary skill in the art would accept the utiltiy statement as obviously valid and correct. Radoev v. Brenner, Ferguson, (POBA 1957) 117 USPQ 229.

Applicants' disclosure fails to provide a description of a method of treating all infectious diseases in a single infected host. Methods of treating a specific condition with a active agent, whether old or new, should be enabled by a written decription containing a statistically significant example, which should include the organism treated. Applicants have not provided such a disclosure. Moreover, applicants' statements with regard to the various dosages and modes of administration of the quinoline compound, for the treatment of all infectious diseases are merely speculative, since nowhere in the specification as filed, is described a method of treating all infectious diseases, *in vivo* in a single patient.

The most critical failure of the specification is the lack of a single specific infectious disease. "Infectious disease" is just a vague umbrella expression. Infections vary from those so benign that they are never treated, to those so virulent that treatment is useless. There are hundreds of different kinds, and there is no broad based anti-infectious agent. In effect, what this specification does is say: Here is the compound. You figure out what disease they might be useful for. This is not the "immediate benefit to the public" that Nelson v. Bowler (206 USPQ 880) refers to. This is just a promising lead, no more.

Thus, applicants' situation is much like that of In re Kirk, 153 USPQ 48: "What the applicants are really saying to those skilled in the art is take the compound, experiment, and find out what it treats".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 and claims 2-5 are substantial duplicates. If claims 2 and 3 are intended to be composition claims, then they are not proper because they fail to recite an inert carrier. The term "medicine" does not distinguish the claims from the compound claims.

Claim 7 fails to recite and effective amount of active ingredient. A mere trace may prove inoperable.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,998,436. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compound is disclosed therein having the same use.

Claims 1-7 are directed to an invention not patentably distinct from claims 1-11 of commonly assigned US 5,998,436. Specifically, the instant compound is generically embraced therein.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US 5,998,436, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.

PATRICIA L. MORRIS
PRIMARY EXAMINER
GROUP 120

plm

July 16, 2002